

**§ 866.3290 Gonococcal antibody test (GAT).**

(a) *Identification.* A gonococcal antibody test (GAT) is an in vitro device that consists of the reagents intended to identify by immunochemical techniques, such as latex agglutination, indirect fluorescent antibody, or radioimmunoassay, antibodies to *Neisseria gonorrhoeae* in sera of asymptomatic females at low risk of infection. Identification of antibodies with this device may indicate past or present infection of the patient with *Neisseria gonorrhoeae*.

(b) *Classification.* Class III (premarket approval) (transitional device).

(c) *Date PMA or notice of completion of a PDP is required.* As of May 28, 1976, an approval under section 515 of the act is required before this device may be commercially distributed. See § 866.3.

[47 FR 50823, Nov. 9, 1982, as amended at 52 FR 17734, May 11, 1987]

**§ 866.3300 *Haemophilus* spp. serological reagents.**

(a) *Identification.* *Haemophilus* spp. serological reagents are devices that consist of antigens and antisera, including antisera conjugated with a fluorescent dye, that are used in serological tests to identify *Haemophilus* spp. directly from clinical specimens or tissue culture isolates derived from clinical specimens. The identification aids in the diagnosis of diseases caused by bacteria belonging to the genus *Haemophilus* and provides epidemiological information on diseases caused by these microorganisms. Diseases most often caused by *Haemophilus* spp. include pneumonia, pharyngitis, sinusitis, vaginitis, chancroid venereal disease, and a contagious form of conjunctivitis (inflammation of eyelid membranes).

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 866.9.

[47 FR 50823, Nov. 9, 1982, as amended at 63 FR 59226, Nov. 3, 1998]

**§ 866.3305 Herpes simplex virus serological assays.**

(a) *Identification.* Herpes simplex virus serological assays are devices that consist of antigens and antisera used in various serological tests to identify antibodies to herpes simplex virus in serum. Additionally, some of the assays consist of herpes simplex virus antisera conjugated with a fluorescent dye (immunofluorescent assays) used to identify herpes simplex virus directly from clinical specimens or tissue culture isolates derived from clinical specimens. The identification aids in the diagnosis of diseases caused by herpes simplex viruses and provides epidemiological information on these diseases. Herpes simplex viral infections range from common and mild lesions of the skin and mucous membranes to a severe form of encephalitis (inflammation of the brain). Neonatal herpes virus infections range from a mild infection to a severe generalized disease with a fatal outcome.

(b) *Classification.* Class II (special controls). The device is classified as class II (special controls). The special control for the device is FDA's revised guidance document entitled "Class II Special Controls Guidance Document: Herpes Simplex Virus Types 1 and 2 Serological Assays." For availability of the guidance revised document, see § 866.1(e).

[72 FR 15830, Apr. 3, 2007, as amended at 74 FR 42775, Aug. 25, 2009; 76 FR 48717, Aug. 9, 2011]

**§ 866.3310 Hepatitis A virus (HAV) serological assays.**

(a) *Identification.* HAV serological assays are devices that consist of antigens and antisera for the detection of hepatitis A virus-specific IgM, IgG, or total antibodies (IgM and IgG), in human serum or plasma. These devices are used for testing specimens from individuals who have signs and symptoms consistent with acute hepatitis to determine if an individual has been previously infected with HAV, or as an aid to identify HAV-susceptible individuals. The detection of these antibodies aids in the clinical laboratory diagnosis of an acute or past infection by HAV in conjunction with other clinical laboratory findings. These devices